(19)

No. 03-388

In the Supreme Court of the United States

DENNIS BATES, *ET AL.*,

Petitioners,

v.

DOW AGROSCIENCES LLC,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF FOR THE PRODUCT LIABILITY ADVISORY COUNCIL, INC., AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

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QUESTION PRESENTED

Whether state law claims for crop injury are preempted by the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-137?

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BRIEF FOR THE PRODUCT LIABILITY ADVISORY COUNCIL, INC., AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

INTEREST OF THE *AMICUS CURIAE*[1]

The Product Liability Advisory Council, Inc. ("PLAC") is a non-profit association with 132 corporate members representing a broad cross-section of American and international product manufacturers. These companies seek to contribute to the improvement and reform of the law in the United States and elsewhere, with emphasis on the law governing the liability of manufacturers of products. PLAC's perspective is derived from the experiences of a corporate membership that spans a diverse group of industries in various facets of the manufacturing sector. Since 1983, PLAC has submitted hundreds of briefs as *amicus curiae* in state and federal courts, including this Court, presenting the broad perspective of product manufacturers seeking fairness and balance in the application and development of the law as it affects product liability. A list of PLAC's corporate members is reproduced in Appendix A.

Because many of PLAC's members manufacture products that are subject to preemptive federal requirements, they have a vital interest in the development of the law of preemption. PLAC has filed briefs in many of this Court's cases involving federal preemption, including *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001); *Geier* v. *American Honda Motor Co.*, 529 U.S. 861 (2000); *Norfolk S.*

[1] The parties have consented to the filing of this brief; the written consents have been filed with the Clerk. This brief was not authored in whole or in part by counsel for a party, and no person or entity other than the *amicus curiae*, its members, and its counsel made a monetary contribution to the preparation and submission of this brief.

Ry. v. *Shanklin*, 529 U.S. 344 (2000); *United States* v. *Locke*, 529 U.S. 89 (2000); and *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996). Most recently, PLAC filed a brief supporting the petitioner in *BASF Corp.* v. *Peterson*, No. 04-81 (petition for cert. filed July 16, 2004), another case involving federal preemption under FIFRA. The petition in *Peterson* remains pending before this Court.

Because PLAC's members sell their products in every state in the nation, they understand the difficulty and costliness of attempting to comply with differing state law standards for product labeling. A single set of federal labeling standards is vastly superior as a matter of both common sense and public policy to a system in which label content is governed by the laws of 50 states. The advantages of a federally mandated labeling scheme are particularly pronounced when compared with state labeling "standards" established in litigation by lay juries applying broad tort principles.

When Congress enacted FIFRA, it wisely decided to establish nationally uniform pesticide labeling standards administered by an expert federal agency. The benefits of that rational, predictable, and consistent labeling system will be substantially eroded if judges and juries evaluating state law claims can second-guess federal law regarding the adequacy of labeling. PLAC believes that when Congress creates comprehensive, federally administered rules governing the labels of products that it regulates, allowing actions that challenge those labels under state law deprives PLAC members of the benefits — including predictability and uniformity — that Congress intended. Accordingly, PLAC has a strong interest in urging the Court to affirm the decision below.

STATEMENT

In the decision below, the Fifth Circuit correctly concluded that FIFRA expressly preempts state law claims, including claims arising from damage to crops, that rest on contentions that a pesticide's labeling is inadequate. In

PLAC's view, well-established principles of implied conflict preemption dictate the same conclusion.

1. *Federal Regulation of Pesticide Labeling.* FIFRA is a "comprehensive regulatory statute" (*Ruckelshaus* v. *Monsanto Co.*, 467 U.S. 986, 991 (1984)) that "creates a comprehensive regulatory scheme for pesticide and herbicide labeling." *Andrus* v. *AgrEvo USA Co.*, 178 F.3d 395, 398 (5th Cir. 1999); see also *Wisconsin Pub. Intervenor* v. *Mortier*, 501 U.S. 597, 601 (1991).[2] FIFRA grants EPA "exclusive supervision" of pesticide labeling. *New York State Pesticide Coalition, Inc.* v. *Jorling*, 874 F.2d 115, 118 (2d Cir. 1989). In a provision entitled "Uniformity," the statute expressly prohibits states from imposing "*any* requirements for labeling or packaging in addition to or different from those required" by EPA. 7 U.S.C. § 136v(b) (emphasis added). Congress intended this provision "to completely preempt State authority in regard to labeling." H.R. Rep. No. 92-511, at 16 (1971). See also *Arkansas-Platte & Gulf P'ship* v. *Van Waters & Rogers, Inc.*, 959 F.2d 158, 160 (10th Cir. 1992) ("*Arkansas-Platte I*") ("A plain reading of the statute indicates [a] * * * specific intent to occupy the field in labeling and packaging"), cert. granted and judgment vacated by *Arkansas-Platte & Gulf P'ship* v. *Dow Chem. Co.*, 506 U.S. 910 (1992).

EPA's authority over pesticide labeling is implemented primarily through the registration process. No pesticide may be sold in the United States unless it has first been registered with EPA. 7 U.S.C § 136a(a). To obtain registration, a pesticide manufacturer must submit to EPA "a complete copy of the labeling" of the pesticide. 7 U.S.C. § 136a(c)(1).[3] See

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[2] Herbicides fall within FIFRA's definition of "pesticide." See 7 U.S.C. § 136(u).

[3] "Labeling" means "all labels and all other written, printed, or graphic matter * * * accompanying the pesticide * * * at any time;

7 U.S.C. § 136a(c)(9). EPA will not register a pesticide unless it determines that its labeling "compl[ies] with the requirements of [FIFRA]." 7 U.S.C. § 136a(c)(5); see also 40 C.F.R. § 152.112(f)). Once approved, the labeling cannot be altered without EPA's permission. See 7 U.S.C. §§ 136j(a)(2)(A), 136(a)(f)(1); 40 C.F.R. § 152.44(a). An EPA regulation affirmatively provides that "[a] registrant may distribute or sell a registered product with the composition, packaging, and labeling currently approved by the Agency." 40 C.F.R. § 152.130(a).

In considering an application for pesticide registration, EPA has the authority to examine whether the pesticide's "composition is such as to warrant the proposed claims for it." 7 U.S.C. § 136a(c)(5). To address a backlog of registration applications, Congress amended FIFRA in 1978 to provide that EPA "*may* register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy" (7 U.S.C. § 136a(c)(5) (emphasis added)) and "*may* waive" requirements for submission of data pertaining to efficacy. *Id.* (emphasis added). EPA has by regulation "waived all requirements to submit efficacy data" in most cases, but requires each registrant to "ensure through testing that his products are efficacious when used in accordance with label directions and commonly accepted pest control practices." 40 C.F.R. § 158.640(b)(1). The agency further "reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration." *Id.* EPA has stated that such a request "may be made for any product for which a pattern of inadequate performance has been reported." 44 Fed. Reg. 27,932, 27,939 (May 11, 1979).

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or * * * to which reference is made on the label or in literature accompanying the pesticide." 7 U.S.C. § 136(p)(2).

EPA has promulgated detailed labeling regulations, which "govern what must (and what cannot) appear on the label." EPA Label Review Manual 1-11 (3d ed. Aug. 2003), *available at* http://www.epa.gov/oppfead1/labeling/lrm/labelreviewmanual.pdf; see also 40 C.F.R. pt. 156 (Labeling Requirements for Pesticides and Devices). The regulations address both the design and content of pesticide labeling. 40 C.F.R. § 156.10. Among other things, they impose requirements for the "Directions for Use," a detailed set of instructions and warnings that *must* appear on the labeling. *Id.* § 156.10(a)(1)(viii). The directions "must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment" (*id.* § 156.10(i)(1)(i)) — including harm to crops.[4]

Although these labeling regulations appear comprehensive, they nonetheless understate EPA's broad and deep involvement in pesticide labeling.

> Because of the variety of pesticide products, purposes and uses, it is impossible for EPA to describe in regulatory form the majority of the individual labeling decisions that are required under the licensing scheme of FIFRA. EPA's labeling regulations in part 156 are of necessity general, serving as a framework for individual decisions and allowing flexibility for both the Agency and applicants to tailor actual labeling to the extent practicable to a particular product and its uses.

66 Fed. Reg. 64,759, 64,761 (Dec. 14, 2001).

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[4] "The term 'environment' includes water, air, land, and *all plants* and man and other animals living therein, and the interrelationships which exist among these." 7 U.S.C. § 136(j) (emphasis added).

Demonstrating the centrality of the label to the federal regulatory regime, a pesticide's labeling determines how it may lawfully be used. It is a violation of FIFRA, punishable by civil and criminal penalties, "to use any pesticide in a manner inconsistent with its labeling." 7 U.S.C. § 136j(a)(2)(G). A statement explaining this limitation must appear on every pesticide label. 40 C.F.R. § 156.10(i)(2)(ii).

EPA's supervision of pesticide labeling continues after a product is granted registration. FIFRA places registrants under an ongoing obligation to report to EPA "additional factual information regarding unreasonable adverse effects on the environment" of the registered pesticide. 7 U.S.C. § 136d(a)(2). The agency regulations implementing this provision require registrants to report instances of harm to crops, including specifically "phytotoxicity to the treated crop," unless "the label provides an adequate notice of such a risk." 40 C.F.R. §§ 159.184(a)(1)-(3), (b)(3)-(4). When it receives information about such unanticipated risks or other problems, EPA may cancel or suspend the pesticide's registration under 7 U.S.C. § 136d(b) or (c). It may also stop short of cancellation or suspension, instead engaging in "closer examination" of a pesticide, making a "request for additional information," or requiring "modifications to the terms and conditions of registration * * * necessitated by the balancing of the risks and benefits associated with a particular pesticide." 62 Fed. Reg. 49,370, 49,372 (Sept. 19, 1997). Such post-registration modifications of the terms and conditions of registration would be likely to include imposition of additional or different labeling requirements, such as "requiring different warning statements, application methods, or the use of personal protective equipment." *Id.* at 49,382.

EPA also may take action under FIFRA if it determines that a pesticide is "misbranded." 7 U.S.C. § 136j(a)(1)(E). A registered pesticide is considered "misbranded" if its labeling contains "any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular." *Id.* § 136(q)(1)(A). A pesticide is also "misbranded" if

> (F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 3(d) of [FIFRA], are adequate to protect health and the environment; [or]
>
> (G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 3(d) of [FIFRA], is adequate to protect health and the environment.

7 U.S.C. § 136(q)(1)(A). A "false or misleading statement concerning the effectiveness of the product as a pesticide" constitutes misbranding as well. 40 C.F.R. § 156.10(a)(5)(ii).

A misbranded product is subject to stop-sale orders and seizure, 7 U.S.C. § 136j, and persons found distributing or selling a misbranded product are subject to civil and/or criminal penalties, *id.* § 136l. EPA has stated that it "wishes to retain the flexibility to choose the appropriate response to evidence of incorrect labeling," based in part on its "day-to-day dealing with individual registrants." 47 Fed. Reg. 40,659, 40,663 (Sept. 15, 1982). "Where a good-faith effort has been made, the registrant should not be penalized unless the magnitude of the error creates serious label discrepancies or could be hazardous if followed by the user." *Id.*

2. *Proceedings Below.* Respondent Dow AgroSciences LLC ("Dow") manufactured and sold its herbicide Strongarm under labeling approved by EPA. Petitioners applied Strongarm to their peanut crops during the 2000 growing season. Petitioners claim that Strongarm "stunted the growth of peanut plants, caused yellowing, inhibited peanuts from lapping or properly developing foliage, delayed maturity, reduced

total peanut production, and increased the expense of harvesting future peanut crops." Pet. App. 2a. According to petitioners, they were unaware that Strongarm "would not be readily absorbed and would retard or injure the roots of the non-target peanut plants" when soil pH levels reached 7.0 or greater. Pet. Br. 9. With EPA's approval, Dow later added to the Strongarm label an instruction that the herbicide should not be applied to soils having a pH of 7.2 or greater. *Id.* at 11.

After petitioners threatened to sue Dow under state law, Dow initiated a federal action seeking a declaration that the farmers' claims were preempted by FIFRA. Pet. App. at 3a. Petitioners filed counterclaims alleging breach of warranty, fraud, defective design, negligence, and violation of the Texas Deceptive Trade Practices Act. *Id.* The district court granted summary judgment to Dow, ruling that FIFRA expressly preempted petitioners' claims because they effectively "challenge[d] the Strongarm label." *Id.* at 25a.

The Fifth Circuit affirmed. Carefully reviewing petitioners' claims, the court of appeals concluded that they all rested on a contention that the Strongarm label was inadequate. It stated: "One cannot escape the heart of the farmers' grievance: Strongarm is dangerous to peanut crops in soil with a pH level over 7.0, and that was not disclosed to them." *Id.* at 18a. Because "a judgment against Dow would induce it to alter its product label" to avoid future liability (*id.* at 15a), the court of appeals held that FIFRA expressly preempted petitioners' claims.

The court of appeals did not closely examine petitioners' contention "[t]hat the EPA had not elected to impose labeling requirements concerning product efficacy." *Id.* at 14a-15a. Observing that "FIFRA's express preemption clause is self-executing," the court of appeals rejected petitioners' assertion that EPA's regulations "define the domain expressly preempted by FIFRA" *Id.* at 14a, 15a (quoting *American Cyanamid Co.* v. *Geye*, 79 S.W.3d 21, 23 (Tex. 2002), cert.

denied, 539 U.S. 969 (2003)). Because it was persuaded that FIFRA expressly preempted petitioners' claims, the court below did not reach Dow's argument that the claims also were foreclosed by implied preemption principles.

SUMMARY OF ARGUMENT

Petitioners argue at length that FIFRA does not expressly preempt their claims because state law damages actions are not "requirements" within the meaning of Section 136v(b). See Pet. Br. 16-28. Even if petitioners' textual argument is correct, it does not follow that their claims may proceed. As this Court has made clear, the presence of an express preemption provision does not preclude the application of ordinary principles of implied conflict preemption. In this case, those principles operate decisively to preempt petitioners' claims, because their challenge to the adequacy of Dow's pesticide labeling undermines the congressional purposes underlying FIFRA.

When it enacted FIFRA, Congress intended to create a nationally uniform pesticide labeling regime under the exclusive direction and control of EPA. EPA has fully exercised that authority by promulgating comprehensive and detailed labeling regulations and reviewing all labeling before registering a pesticide. Both national uniformity and EPA's authority would be severely compromised if manufacturers were subject to damages liability because their labeling failed to satisfy state law tort standards. The need to anticipate and comply with the tort regimes of 50 states would adversely affect the quality of pesticide labels, hamper the interstate distribution of pesticides, impose unacceptable burdens on the federal registration process, and create untenable conflicts between federal and state law.

The amendment of FIFRA to authorize EPA's waiver of product efficacy data submission before registration does not cast doubt on the conclusion that FIFRA forecloses state law actions asserting damage to crops. Contrary to petitioners'

contentions, EPA continues to monitor product efficacy and to prohibit false or misleading efficacy claims on product labeling. After enacting the waiver authorization, moreover, Congress re-affirmed its commitment to federal control over labeling by re-enacting Section 136v(b) with its new subheading, "Uniformity." Because petitioners' claims boil down to the contention that Dow omitted an important instruction from its labeling, their action conflicts with the goal of uniformity and is impliedly preempted.

ARGUMENT

I. FIFRA'S EXPRESS PREEMPTION CLAUSE DOES NOT PRECLUDE A FINDING THAT PETITIONERS' STATE LAW CLAIMS ARE IMPLIEDLY PREEMPTED

By operation of the Supremacy Clause, U.S. Const. art. VI, cl. 2, state laws that "interfere with, or are contrary to" federal law (*Hillsborough County, Fla.* v. *Automated Med. Labs., Inc.*, 471 U.S. 707, 712 (1985) (internal quotation marks omitted)) are "without effect." *Maryland* v. *Louisiana*, 451 U.S. 725, 746 (1981). Federal law will not be deemed to override state law unless that is "the clear and manifest purpose of Congress." *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Preemption "is compelled," however, "whether Congress's command is explicitly stated in the statute's language or implicitly contained in its structure and purpose." *First Fidelity Sav. & Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141, 153 (1982) (quoting *Jones* v. *Rath Packing Co.*, 430 U.S. 519, 525 (1977)).

State law is implicitly preempted when "a scheme of federal regulation is 'so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it.'" *Mortier*, 501 U.S. at 605 (quoting *Rice*, 331 U.S. at 230). "Even where Congress has not completely displaced state regulation in a specific area, state law is nullified to the extent that it actually conflicts with federal law." *First Fidelity Sav. & Loan Ass'n* v. *de la Cuesta*, 458 U.S. at 153. Such a conflict exists when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 873 (2000) (quoting *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941)). Conflict preemption applies "whether that 'obstacle' goes by the name of 'conflicting; contrary to; . . . repugnance; difference; irreconcilability; inconsistency; violation; curtailment; . . . interference,' or the like." *Id.* (quoting *Hines*, 312 U.S. at 67) (omissions in original).

"[N]either an express pre-emption provision nor a saving clause 'bar[s] the ordinary working of conflict pre-emption principles.'" *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001) (quoting *Geier*, 529 U.S. at 869). See also *Freightliner Corp.* v. *Myrick*, 514 U.S. 280, 287 (1995) (dismissing as "without merit" the suggestion "that implied pre-emption cannot exist when Congress has chosen to include an express pre-emption clause in a statute"); *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 503 (1996) (after finding no express preemption under the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act, observing that common law claims might still "be preempted under conflict pre-emption analysis"); *Boggs* v. *Boggs*, 520 U.S. 833 (1997) (employing implied conflict preemption analysis to decide case under the Employee Retirement Income Security Act despite presence of an express preemption clause). Thus, express and implied preemption are not mutually exclusive: a federal statute may preempt state law either or both ways. See *Geier*, 529 U.S. 861, 869 (2000) (citing *Freightliner*, 514 U.S. at 280). Put another way, the conclusion that a statute's express preemption provision does *not* nullify a particular state law does not preclude a finding that the state law is impliedly preempted. *Id.*

Before this Court decided *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992), several federal courts of appeals had concluded that, given Congress's evident intent to create

a uniform scheme of pesticide labeling, FIFRA *impliedly* preempts state law damages actions that, if successful, would induce the manufacturer to change its label. See *Arkansas-Platte I*, 959 F.2d at 162; *Papas* v. *Upjohn Co.*, 926 F.2d 1019, 1020 (11th Cir. 1991) ("*Papas I*"), cert. granted and judgment vacated by *Pappas* v. *Zoecon Corp.*, 505 U.S. 1215 (1992). Petitions for certiorari were pending in both *Arkansas-Platte I* and *Papas I* when *Cipollone* was decided. The Court ruled in *Cipollone* that the Federal Cigarette Labeling and Advertising Act, which contains a provision having language similar to Section 136v(b) of FIFRA, *expressly* preempts certain state law damages actions. Thereafter, the Court granted, vacated, and remanded both *Arkansas-Platte I* and *Papas I* for further consideration in light of *Cipollone*. *Arkansas-Platte & Gulf P'ship* v. *Dow Chem. Co.*, 506 U.S. 910 (1992); *Papas* v. *Zoecon Corp.*, 505 U.S. 1215 (1992).

Considering those cases on remand, the Tenth and Eleventh Circuits held in light of *Cipollone* that Section 136v(b) of FIFRA *expressly* preempts state law damages actions, including failure-to-warn claims, that challenge pesticide labels. See *Arkansas-Platte & Gulf P'ship* v. *Van Waters & Rogers, Inc.*, 981 F.2d 1177, 1179 (10th Cir.) ("*Arkansas-Platte II*") ("We believe Congress circumscribed the area of labeling and packaging and preserved it only for federal law."), cert. denied, 510 U.S. 813 (1993); *Papas* v. *Upjohn Co.*, 985 F.2d 516, 518 (11th Cir.) ("*Papas II*") (holding that "the *Cipollone* opinion dictates, under an express preemption analysis, the same result we reached earlier under the implied preemption doctrine"), cert. denied, 510 U.S. 913 (1993). Since *Cipollone*, most courts considering whether FIFRA preempts state law damages claims — including the Fifth Circuit in the decision below — have analyzed the issue under express preemption principles. See, *e.g.*, *MacDonald* v. *Monsanto Co.*, 27 F.3d 1021, 1025 (5th Cir. 1994); *Taylor AG Indus.* v. *Pure-Gro*, 54 F.3d 555, 560 (9th Cir, 1995).[5]

Nevertheless, implied preemption remains a viable and important part of the analysis of whether FIFRA forecloses a state law claim. Even if a claim falls outside the express terms of Section 136v(b), a court nonetheless may find that it is implicitly preempted by FIFRA or its regulations. The Ninth Circuit, for example, recently relied on implied preemption in dismissing a state law claim raising allegations that the defendant lied to EPA to obtain approval of label directions that precluded its customers' use of the plaintiff's product. See *Nathan Kimmel, Inc.* v. *DowElanco*, 275 F.3d 1199, 1204 (9th Cir. 2002). The court stated that it was unnecessary "to determine the exact length of the preemptive shadow cast by the express language of § 136v * * * because ordinary conflict principles dictate that [plaintiff's] state law claim is *impliedly* preempted by FIFRA." *Id.* (emphasis in original).

If the Court is not persuaded that Section 136v(b) expressly preempts petitioners' claims — for example, if it accepts petitioners' argument that state law actions seeking damages for past harms do not impose "requirements" — it should examine whether the claims are impliedly preempted. See *Buckman*, 531 U.S. at 348 & n.2 (expressing no view as to whether the claims at issue were subject to express preemption in light of the Court's conclusion that such claims were impliedly preempted). As we discuss below, implied preemption provides a valid alternative ground for affirming the Fifth Circuit's decision. See *SEC* v. *Chenery Corp.*, 318 U.S. 80, 88 (1943) (describing "the settled rule that, in re-

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[5] Indeed, some courts of appeals construed *Cipollone* to preclude a finding of implied preemption under FIFRA. See, *e.g.*, *Taylor AG Indus.*, 54 F.3d at 560. This Court has since made clear that this is an incorrect reading of *Cipollone*. See *Freightliner*, 514 U.S. at 287.

viewing the decision of a lower court, it must be affirmed if the result is correct 'although the lower court relied upon a wrong ground or gave a wrong reason'" (quoting *Helvering* v. *Gowran*, 302 U.S. 238, 245 (1937))); see also *Schenck* v. *Pro-Choice Network*, 519 U.S. 357, 384 (1997) (same).

II. FIFRA IMPLIEDLY PREEMPTS STATE LAW CLAIMS, INCLUDING CLAIMS FOR CROP INJURY, ARISING FROM ALLEGED FLAWS IN PESTICIDE LABELING

Petitioners' state law claims conflict with Congress's objective to create a nationally uniform pesticide labeling regime under the exclusive supervision of EPA. Moreover, they are incompatible with the substantive statutory and regulatory provisions that further this goal. Accordingly, FIFRA and its regulations impliedly preempt petitioners' claims. Contrary to petitioners' argument (Pet. Br. 30-37), EPA's decision to discontinue the routine review of product efficacy data prior to registration — an action that had no direct impact on EPA's firm control over pesticide *labeling* — does not undercut that conclusion.

A. Congress Intended To Create A Uniform Pesticide Labeling Regime Under EPA's Exclusive Control

FIFRA's text, structure, and legislative history demonstrate that Congress intended to create a nationally uniform system of pesticide labeling administered exclusively by EPA. That purpose is expressed unmistakably in the text of Section 136v(b), including its title, which was added in 1988. See, *e.g.*, Act of Oct. 25, 1988, Pub. L. No. 100-532, 102 Stat. 2654 (adding subheading "Uniformity" to Section 136v(b)); S. Rep. No. 95-334, at 4 (1977) (characterizing EPA-approved product labeling as "the final authority" governing the application of a pesticide); *MacDonald*, 27 F.3d at 1024 (describing § 136v(b) as "an effort to preserve uniformity of laws concerning labeling"); *Arkansas-Platte I*, 959 F.2d at 162 (purpose of § 136v(b) is to "ensure uniform labeling standards"); *Papas I*, 926 F.2d at 1025 (stating that Congress has endorsed objective of obtaining nationwide uniformity in labeling).

That goal also is apparent in FIFRA's substantive provisions. The statute requires EPA to review the labeling of every pesticide marketed anywhere in the country (7 U.S.C. § 136a(c)(1)), establishes standards for that labeling (*id.* §§ 136a(c)(5), 136j(a)(1)(E)), and forbids pesticide use that is inconsistent with that labeling (*id.* § 136j(a)(2)(G)). These provisions reinforce Section 136v(b)'s message that state law has no role to play in determining the adequacy of pesticide labeling. It is inconceivable that Congress would have required EPA to review all pesticide labeling, instructed the agency what to consider in evaluating the labeling, and mandated that users follow the labeling, if it did not expect EPA to have the final say on the contents of the labeling.

Furthermore, "[f]ederal regulations have no less preemptive effect than federal statutes," and their force "does not depend on express congressional authorization to displace state law." *First Fidelity Sav. & Loan Ass'n* v. *de la Cuesta*, 458 U.S. at 153, 154 (1982). Acting well within its authority under FIFRA, EPA has asserted complete control over federal labeling by issuing comprehensive labeling requirements, reviewing every label, and providing that pesticides may be sold under their approved labeling. See 40 C.F.R. § 152.130(a). These regulations leave no room for contrary or additional state law requirements.

B. State Law Damages Actions That Challenge The Adequacy Of Pesticide Labels Would Undermine FIFRA's Goals

As this Court recently stated in *Geier*, a congressional policy of nationwide regulatory uniformity "favors preemption of state tort suits." 529 U.S. at 871. That is because

> the rules of law that judges and juries create or apply in such suits may themselves similarly create uncertainty and even conflict, say, when different juries in different States reach different decisions on similar facts.

Id. The Court's observation in *Geier* applies fully here: allowing state law damages actions would substantially erode the benefits of the nationally uniform pesticide labeling scheme created by FIFRA. See *Arkansas-Platte I*, 959 F.2d at 162 ("State court damage awards * * * would constitute ad hoc determinations of the adequacy of statutory labeling standards [which] would hinder the accomplishment of the full purpose of 136v(b), which is to ensure uniform labeling standards.").

Labeling-related claims such as those asserted by petitioners allow courts and juries "to sit, in effect, as super-EPA review boards," second-guessing the content of EPA-approved labeling. *Welchert* v. *American Cyanamid, Inc.*, 59 F.3d 69, 73 (8th Cir. 1995). If pesticide manufacturers were subject to liability for failure of their labels to satisfy state-imposed tort standards, they would have to wind through the variations of 50 states' tort-law systems, rather than federal law alone, when making labeling decisions. Such a radical change in the regulation of pesticide labeling would have predictably adverse consequences.

1. "As a practical matter, complying with the [agency's] detailed regulatory regime in the shadow of 50 States' tort regimes [would] dramatically increase the burdens facing potential [registrants] — burdens not contemplated by Congress in enacting" FIFRA. *Buckman*, 531 U.S. at 350. No pesticide may be marketed in the United States unless EPA first approves the label (7 U.S.C. § 136a(c)(5)), and proposed label changes must be pre-cleared (*id.* § 136a(f)(1)). If state law played a role in determining label content, the agency would be overwhelmed (and registrants burdened) with requests for approval of label changes and state-specific variations.

The flood of requests for approval of label changes would portend more serious problems, because the agency's judgments about what should be included on the label no longer would be authoritative. Although EPA might conclude that a particular warning or instruction was unnecessary or counterproductive, a manufacturer facing state law liability for lack of that warning or instruction would be hard-pressed to exclude it. There would be no effective way to mediate such clashes between EPA's expert views and the vagaries of state jury verdicts. The conflict would be made more acute by FIFRA's provision that no pesticide may be used "in a manner inconsistent with its labeling." 7 U.S.C. § 136j(a)(2)(G).

For example, a loss in state court litigation might impel a manufacturer to instruct against use of its pesticide in combination with another chemical. If included on the labeling, such an instruction would make a farmer's use of the combined products illegal under FIFRA. *Id.* EPA might deem the combination perfectly safe, however, and thus object to the proposed labeling change. The manufacturer then would face the unhappy choice of complying with EPA's directions or complying with state law — but could not do both. When conflicting state and federal requirements make simultaneous compliance impossible, the state law is preempted. See *Freightliner*, 514 U.S. at 287.

Petitioners contend that their claims reinforce rather than conflict with FIFRA's "misbranding prohibitions" because they "giv[e] a remedy to injured farmers for the pesticide manufacturer's failure to ensure that its label is accurate." Pet. Br. 37. But FIFRA expressly authorizes EPA, not lay juries, to determine whether pesticide labeling meets federal standards *and* to decide on the proper response to a violation. See, *e.g.*, 7 U.S.C. § 136g(c)(1) (authorizing EPA to deter-

mine "whether [pesticides] comply with the requirements" of FIFRA); *id.* § 136k(a) (authorizing EPA to forbid the sale or use of any pesticide if it has "reason to believe * * * that such pesticide * * * is in violation of any of the provisions of this subchapter"); § 136q(b)(1)-(6) (authorizing EPA to recall a pesticide); § 136d(b) (authorizing EPA to cancel the registration of a pesticide).[6] EPA is required to consider the impact of its response "on production and prices of agricultural commodities, retail food prices, and otherwise on the national economy." *Id.*

Even if the "standards imposed by federal law" (Pet. Br. 38) could be enforced by jurors evaluating *state law* causes of action, as petitioners implausibly suggest, such actions would undermine EPA's "flexibility to choose the appropriate response to evidence of incorrect labeling." 47 Fed. Reg. at 40,663. Accordingly, petitioners' argument that their claims impose requirements *consistent* with FIFRA does not allow them to avoid implied preemption.

2. In the absence of preemption, EPA might be forced to accede to requests for litigation-focused labeling changes to avoid having the manufacturer simply de-register the pesticide to avoid liability. Under that scenario, pesticide labeling would lose much of its value as a clear, consistent, and reliable mechanism for conveying to users the essential information about pesticides and their proper use. Users accustomed to standard labeling, with form and content approved by a single expert decision-maker, would face a Tower of Babel: pesticides would bear discordant and inscrutable warnings derived from litigation, or fear of litigation, under the differing laws of 50 different jurisdictions.

[6] In addition, FIFRA and its regulations provide for the imposition of administrative, civil, and criminal penalties for violations. See 7 U.S.C. § 136l(a) and (b); 40 C.F.R. pt. 22.

Under a state law driven labeling regime, manufacturers would use inconsistent language to describe the risks associated with their products. For example, a manufacturer headquartered in a state with stringent product liability laws might include very strongly worded warnings on its labeling, while a manufacturer located elsewhere, marketing a pesticide with the exact same risk profile, might include fewer warnings or none at all. Faced with such different warning currencies, users would have difficulty comparing the benefits and risks of using different products, making the market a less efficient mechanism for weeding out riskier pesticides.

Even worse, pesticide users would be forced to monitor and evaluate a constantly changing set of warnings, as the labels evolved over time in response to litigation and changing state standards. Although some labeling changes might be justified by new information, others might be prompted by arbitrary jury verdicts, unfavorable settlements, or the mere threat of litigation. Because pesticide users would have no way to distinguish serious warnings from frivolous ones, they might insufficiently heed important new cautions or overreact to purely protective disclaimers.

In the end, the warnings and instructions on pesticide labeling no longer would reflect the considered judgments of manufacturers and the learned agency that supervises them. Instead, label content would be imposed by lay judges and jurors, who might have sympathy for local farmers but lack any special understanding of pesticides or the broader national interests that now inform their regulation. The addition of disclaimers over time would lead to overcrowded labels and "warning fatigue," a danger that has been recognized by many courts, including this one. See, *e.g.*, *Morales* v. *TWA, Inc.*, 504 U.S. 374, 390 (1992) (agreeing with the FTC that "'[r]equiring too much information in advertisements can have the paradoxical effect of stifling the information that consumers receive'" (alteration in original)); *Witty* v. *Delta Air Lines, Inc.*, 366 F.3d 380, 385 (5th Cir. 2004)

("[W]arnings by their nature conflict, in the sense that the import of one warning is diluted by additional warnings that might be imposed under state law."); *Hood* v. *Ryobi Am. Corp.*, 181 F.3d 608, 611 (4th Cir. 1999) ("Well-meaning attempts to warn of every possible accident lead over time to voluminous yet impenetrable labels * * * ."). Users inevitably would lose confidence in the labels, and FIFRA's strong policy that the labeling should guide all pesticide use would be substantially undermined.

3. A tort-driven labeling system also would burden the interstate distribution of pesticides. Although some manufacturers might use monolithic labels designed to satisfy the tort regimes of *all* states at once — thus including on all labels the warnings and limitations mandated by the most restrictive states — others would sell their products bearing different labels in different states. Thus, they would have to carefully tailor the production and shipment of appropriately packaged pesticides to the anticipated demand in each state, with failure to do so leading to inefficient surpluses and shortages. The added complexity of the distribution chain might cause manufacturers to limit their product lines, stop serving niche markets, or pull out of less profitable or more litigious geographic markets entirely.

Manufacturers wishing to simplify their labels also might simply avoid certain states and certain crop markets. Farmers living in notoriously plaintiff-friendly states or growing low-acreage, high-value crops might discover that there were no pesticides available to meet their needs. This would damage farmers economically and create risk to the food supply.

4. Another case pending before the Court illustrates how label-based state law claims can clash with the federal regulatory regime under an overly narrow view of preemption. In *BASF Corp.* v. *Peterson*, No. 04-81 (petition for cert. filed

July 16, 2004),[7] a pesticide manufacturer was sued in Minnesota state court under New Jersey's consumer protection statute by a nationwide class of farmers. The farmers claimed that the defendant had acted unconscionably by omitting certain crops from the list of approved uses on its pesticide's labeling. That labeling decision was authorized by EPA's "subset labeling" regulation (40 C.F.R. § 152.130(b)), which states that manufacturers may omit federally registered uses from final product labeling. Nevertheless, the Minnesota Supreme Court upheld a $52 million judgment in favor of the plaintiffs.

If *Peterson* is allowed to stand, manufacturers will be reluctant to take advantage of the labeling flexibility provided by EPA's rule, lest they suffer liability under some state's consumer fraud laws. This will undermine EPA's sound policy reasons for adopting the rule. Such clashes between broadly worded state law causes of action and the federal labeling regime will multiply exponentially unless the Court strongly affirms that state law damages actions challenging pesticide labels are preempted by FIFRA.

C. Notwithstanding EPA's Partial Waiver Of Efficacy Data Submission Requirements, FIFRA Preempts Petitioners' Label-Based Claims

According to petitioners, FIFRA does not preempt *their* claims — or any other claims seeking compensation for crop damage — because "Congress has expressly permitted EPA to waive any evaluation of the efficacy of pesticides prior to registration." Pet. Br. 30. "Because FIFRA no longer imposes a duty on EPA to evaluate the efficacy of any federally registered pesticide" (*id.*), they contend, their action would not interfere with any labeling requirement imposed under

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[7] As noted in PLAC's statement of interest, PLAC filed an *amicus* brief supporting the petition in *Peterson*.

FIFRA.[8] As we discuss below, however, the limited waiver of efficacy data submission and review requirements casts no doubt on the conclusion that FIFRA impliedly preempts all label-based state law claims, including claims arising from damage to crops.

1. The waiver of efficacy data submission and review requirements did not create a regulatory vacuum needing to be filled by state law. Contrary to petitioners' contention that product efficacy is now "unmonitored" (Pet. Br. 36), EPA remains actively involved in regulating product efficacy as it relates to labeling. See, *e.g.*, *Etcheverry* v. *Tri-Ag Serv., Inc.*, 993 P.2d 366, 375 (Cal. 2000) (rejecting "the argument that pesticide efficacy will go 'largely, or entirely, unregulated' if state law failure-to-warn claims are preempted"). "What has changed over time is the manner in which EPA is assured of product efficacy." 64 Fed. Reg. 50,672, 59,674 (Sept. 17, 1999).

Although the agency generally does not require manufacturers to submit efficacy data in the first instance, it *does* require manufacturers to *conduct* efficacy testing. EPA retains the power to request submission of the data and invokes this power whenever it has any reason for concern about the efficacy of a product. Moreover, EPA requires manufacturers to inform the agency of crop damage or other adverse events when the risk of those events has not been disclosed on the label. 40 C.F.R. §§ 159.184(a)(1)-(3), (b)(3)-(4). This activity — which brings to EPA's attention the same incidents that otherwise would give rise to private lawsuits — allows EPA to enforce its rule prohibiting the inclusion on pesticide labeling of "any false or misleading statement concerning the effectiveness of the product." 40 C.F.R. § 156.10(a)(5)(ii).

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[8] As used by petitioners, the term "efficacy" encompasses the pesticide's tendency to harm crops to which it is applied. *Id.* We adopt that same convention here.

Thus, the efficacy data waiver did not signal EPA's abandonment of the subject, but instead reflected the agency's judgment that its review of efficacy data prior to registration was unnecessary to its goals. Indeed, when it authorized EPA to waive review of efficacy data, Congress indicated that this authority should be invoked only when "the Administrator found that some other procedure for assuring the efficacy of pesticide products appeared to be sufficient." H.R. Rep. No. 95-663, at 27 (1977), *reprinted in* 1978 U.S.C.C.A.N., at 2000. When it ultimately did waive efficacy-data submission requirements, EPA pointed to "a general belief among persons in the pesticide industry, the U.S. Department of Agriculture and the agricultural community that the efficacy of agricultural pesticides can be effectively regulated by the marketplace (in conjunction with extension services and university research personnel)." 44 Fed. Reg. 27,932, 27,938 (May 11, 1979). In EPA's judgment, this belief proved correct: when EPA later "decided to retain the provisions concerning the waiver of efficacy data," it observed that it had "not been apprised of any increase in the number of ineffective pesticide products on the market." 48 Fed. Reg. 34,000, 34,003 (July 26, 1983).

Thus, EPA has repeatedly reaffirmed its initial judgment that its up-front review of manufacturers' efficacy data is superfluous. If preemption of state law claims nonetheless turned on EPA review of such data, however, registrants "would then have the incentive to submit a deluge of information that the [agency] neither wants nor needs, resulting in additional burdens on the [agency's] evaluation of an application" for registration. *Buckman*, 531 U.S. at 351. This would frustrate Congress's purposes in authorizing EPA to waive efficacy data submission requirements and EPA's purposes in exercising that authority.

2. When it amended FIFRA to permit *EPA* to waive its initial review of product efficacy data, Congress gave no hint that it intended to open the door to *state* regulation of pesti-

cide labeling on issues relating to product efficacy. To the contrary, after authorizing EPA to waive efficacy-data submission requirements, Congress reaffirmed its commitment to nationally uniform pesticide labels by reenacting Section 136v(b), making its intentions even more clear by adding the sub-heading "Uniformity." See Act of Oct. 25, 1988, Pub. L. No. 100-532, 102 Stat. 2654. EPA, for its part, did not eliminate its substantive requirements for pesticide labeling. The efficacy data waiver thus does not alter the implied preemption analysis.

3. Notwithstanding petitioners' effort to characterize their claims as falling within an area that EPA does not regulate, their action strikes at the core of EPA's congressionally mandated authority over pesticide labeling. As the court of appeals explained, petitioners' claims boil down to the contention that Strongarm's labeling failed to instruct them that it should not be used on high-pH soils. Pet. App. 18a. This is precisely the type of instruction that EPA's labeling standards squarely govern. See 40 C.F.R. § 156.10(a)(1)(viii). As discussed above, state law actions imposing such labeling standards conflict with the labeling regime that FIFRA creates. See pages 16-19, *supra*.

CONCLUSION

The decision below should be affirmed.

Respectfully submitted.

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APPENDIX A

PLAC MEMBERS

3M
Allegiance Healthcare Corporation
Altec Industries
American Suzuki Motor Corporation
Andersen Corporation
Anheuser-Busch Companies
Ansell Healthcare, Inc.
Appleton Papers, Inc.
Aventis Pharmaceuticals Inc.
BASF Corporation
Baxter International, Inc.
Bayer Corporation
Beretta U.S.A Corp.
BIC Corporation
Biro Manufacturing Company Inc.
Black & Decker (U.S.) Inc.
BMW of North America, LLC
Bombardier Recreational Products
BP Amoco Corporation
Bridgestone/Firestone, Inc.
Briggs & Stratton Corporation
Bristol-Myers Squibb Company
Brown and Williamson Tobacco
Brown-Forman Corporation
Brunswick Corporation
C. R. Bard, Inc.
Caterpillar Inc.
Chevron Corporation
Compaq
Continental Tire North America, Inc.
Cooper Tire and Rubber Company
Coors Brewing Company
Crown Equipment Corporation

DaimlerChrysler Corporation
Dana Corporation
Deere & Company
E & J Gallo Winery
E. I. DuPont de Nemours and Company
Eaton Corporation
Eli Lilly and Company
Emerson Electric Co.
Engineered Controls International, Inc.
Estee Lauder Companies
ExxonMobil Corporation
FMC Corporation
Ford Motor Company
General Electric Company
General Motors Corporation
Georgia-Pacific Corporation
GlaxoSmithKline
Great Dane Limited Partnership
Guidant Corporation
Harley-Davidson Motor Company
Harsco Corporation, Gas & Fluid Control Group
Honda North America, Inc.
Hyundai Motor America
International Truck and Engine Corporation
Isuzu Motors America, Inc.
Johnson & Johnson
Johnson Controls, Inc.
Joy Global Inc.
Kawasaki Motors Corp., U.S.A.
Kia Motors America, Inc.
Kolcraft Enterprises, Inc.
Kraft Foods North America, Inc.
Lincoln Electric Holdings, Inc.
Mazda (North America), Inc.
Medtronic, Inc.
Mercedes-Benz of North America, Inc.

Michelin North America, Inc.
Miller Brewing Company
Mitsubishi Motors R & D of America, Inc.
Niro Inc.
Nissan North America, Inc.
Novartis Pharmaceuticals Corporation
Otis Elevator Company
PACCAR Inc
Panasonic
Pentair, Inc.
Pfizer Inc.
Pharmacia Corporation
Philip Morris Companies Inc.
Polaris Industries, Inc.
Porsche Cars North America, Inc.
Raytheon Aircraft Company
Rheem Manufacturing
RJ Reynolds Tobacco Company
Schindler Elevator Corporation
SCM Group USA Inc.
Sears, Roebuck and Co.
Shell Oil Company
Siemens Corporation
Smith & Nephew, Inc.
Snap-on Incorporated
Sofamor Danek, Medtronic Inc.
Solutia Inc.
Sturm, Ruger & Company, Inc.
Subaru of America, Inc.
Sunbeam Corporation
Synthes (U.S.A.)
Textron Inc.
The Boeing Company
The Dow Chemical Company
The Goodyear Tire & Rubber Company
The Heil Company

The Procter & Gamble Company
The Raymond Corporation
The Sherwin-Williams Company
The Toro Company
Thomas Built Buses, Inc.
Toshiba America Incorporated
Toyota Motor Sales, USA, Inc.
TRW Inc.
UST (U.S. Tobacco)
Volkswagen of America, Inc.
Volvo Cars of North America, Inc.
Vulcan Materials Company
Water Bonnet Manufacturing, Inc.
Whirlpool Corporation
Wilbur-Ellis Company
Wyeth
Yamaha Motor Corporation, U.S.A.
Zimmer, Inc.